



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0796; FRL-9907-25]

#### Ipconazole; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of ipconazole in or on vegetable, legume, group 6. Chemtura Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0796, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

#### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0796 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0796, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of December 19, 2012 (77 FR 75082) (FRL-9372-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8076) by Chemtura Corporation, 199 Benson Rd, Middlebury, CT 06749. The petition requested that 40 CFR 180.646 be amended by establishing tolerances for residues of the fungicide ipconazole (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) in or on legume vegetables, succulent or dried, crop group 6 at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

## **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and

in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ipconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ipconazole follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Ipconazole has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It causes low to mild irritation to the eyes and skin; it is not a dermal sensitizer. Ipconazole may cause local, portal-of-entry irritation via all routes following repeated exposure. Systemic effects that were noted in dogs, mice, rabbits and/or rats following exposure to ipconazole were generally limited to decreased body weight, body weight gain, and food consumption; and liver and kidney effects. Developmental effects were observed only at the maternally-toxic dose. No consistent evidence of neurotoxicity was

observed following acute, subchronic, or chronic dosing in multiple species in the available ipconazole database and the triazole fungicides as a group typically show either no evidence of neurotoxicity or neurotoxicity at doses significantly higher than the regulatory points of departure. Ipconazole is classified as not likely to be a human carcinogen and there is no concern for mutagenicity. Specific information on the studies received and the nature of the adverse effects caused by ipconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Revised Ipconazole Human Health Risk Assessment of the Proposed Use on Legume Vegetables (Crop Group 6)” on page 23 in docket ID number EPA-HQ-OPP-2012-0796.

*B. Toxicological Points of Departure (POD)/Levels of Concern (LOC)*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological POD and LOC to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (SF) are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some

degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for ipconazole used for human risk assessment is shown in the following Table of this unit.

**Table — Summary of Toxicological Doses and Endpoints for ipconazole for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age)	NOAEL = 10 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1mg/kg/day	Co-critical developmental toxicity studies in rats and rabbits LOAEL <sub>rats</sub> = 30 mg/kg/day, based on increased visceral and skeletal variations LOAEL <sub>rabbis</sub> = 50 mg/kg/day, based on increased incidence of skeletal variations and malformations
Acute dietary (general population including infants and children)	No appropriate endpoint attributable to a single dose of ipconazole was identified for this population.		
Chronic dietary (all populations)	NOAEL = 1.5 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.015 mg/kg/day cPAD = 0.015 mg/kg/day	Chronic toxicity study in dogs LOAEL = 5 mg/kg/day, based on skin reddening (both sexes) and decreased body weight gain in females
Cancer (oral,	No evidence of carcinogenicity. Classification: Not likely to be a		

dermal, inhalation)	human carcinogen, based on two adequate rodent carcinogenicity studies.
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FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ipconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing ipconazole tolerances in 40 CFR 180.646. EPA assessed dietary exposures from ipconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No acute endpoint attributable to a single exposure and relevant for the general population was identified in the toxicity database for ipconazole. A developmental endpoint suitable for acute assessment was identified; therefore an acute dietary assessment was performed only for women of child-bearing age (females 13-49 years old). In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database, Version 3.16 (DEEM-FCID), which uses food consumption information from the U.S. Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Surveys of What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance level residues and 100% crop treated.



ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Surveys of What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance level residues and assumed 100% crop treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that ipconazole is not a likely carcinogen. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for ipconazole. Tolerance level residues and/or 100% crop treated were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for ipconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ipconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS), and Pesticide Root Zone Model Ground Water (PRZM GW) models, the estimated drinking water concentrations (EDWCs) of ipconazole for acute exposures are estimated to be 0.173 parts per billion (ppb) for surface water and 1.01 ppb for ground water.

The EDWCs of ipconazole for chronic exposures for non-cancer assessments are estimated to be 0.105 ppb for surface water and 0.822 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 1.01 ppb was used to assess the contribution from drinking water. For chronic dietary risk assessment, the water concentration of value 0.822 ppb was used to assess the contribution from drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Ipconazole is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Ipconazole is a member of the conazole class of pesticides. Although conazoles act similarly in plants by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a

variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events, including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no conclusive data to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

Ipconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and three triazole conjugates (triazolylalanine, triazolylacetic acid, and triazolylpyrivic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including ipconazole, U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10x FQPA SF for the protection of infants and children. The assessment includes evaluations of risks for various subgroups,

including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at <http://www.regulations.gov>, Docket Identification (ID) Number EPA-HQ-OPP-2005-0497.

An updated dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP) was conducted completed in May 2013, in association with a registration request for several other triazole fungicides. That analysis concluded that risk estimates were below the Agency's level of concern for all population groups. After inclusion of ipconazole uses covered by this action, aggregate risk estimates for T, TA, TAA, and TP for all durations of exposure and for all population subgroups are below the Agency's level of concern. This updated assessment may be found on <http://www.regulations.gov> by searching for the following title and docket number:

“Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address The New Section 3 Registrations For Use of Prothioconazole on Bushberry Crop Subgroup 13-07B, Low Growing Berry, Except Strawberry, Crop Subgroup 13-07H, and Cucurbit Vegetables Crop Group 9; Use of Flutriafol on Coffee; and Ipconazole on Crop Group 6” (located in docket ID number EPA-HQ-OPP-2012-0876).

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10x) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10x, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Offspring effects only occurred in the presence of maternal toxicity and were not considered more severe than the parental effects. Therefore, EPA concluded that there is no quantitative or qualitative evidence of increased susceptibility to rat or rabbit fetuses exposed *in utero* and/or post-natally to ipconazole.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for ipconazole is complete. The Agency waived the requirement for an Immunotoxicity study for ipconazole as there is minimal evidence that ipconazole targets the immune system, nor are the conazoles of a chemical class expected to have an adverse effect on the immune system. An increase in leukocytes was observed in females at 78.3 mg/kg/day in the 28-day inhalation study, however this was not of concern because it was the only evidence of potential immunotoxicity in the entire ipconazole database, the effect occurred at a dose 10-fold higher than the dose (7.8 mg/kg/day) that caused portal-of-entry effects in the same study, and the effect occurred at a dose much greater than the PODs chosen for risk assessment. The overall weight of evidence suggests that ipconazole does not target the immune system.

- ii. There is no consistent evidence of neurotoxicity in the available databases.

Clinical signs suggestive of neurotoxicity were observed in the *in vivo* mammalian cytogenetics study; however, they were seen at relatively high doses, which far exceed the anticipated dietary exposure, and no other signs were observed in any of the other studies, including studies with neurotoxicity assessments. Based on the lack of evidence in the database, EPA waived the requirement for the acute neurotoxicity study. Also, the subchronic neurotoxicity study requirement is considered to be satisfied by the neurotoxicity assessments performed in both the rat subchronic and chronic toxicity/carcinogenicity studies in which no signs of neurotoxicity were observed. This is consistent with what is known about the triazole fungicides as a class, which typically show either no evidence of neurotoxicity or neurotoxicity at doses significantly higher than the regulatory points of departure. Therefore, ipconazole is not considered to be neurotoxic and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

- iii. There is no evidence that ipconazole results in increased susceptibility following *in utero* exposure for rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study, and there are no residual uncertainties with respect to pre- or postnatal exposure.

- iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to ipconazole in drinking water. These assessments will not underestimate the exposure and risks posed by ipconazole.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to ipconazole will occupy <1% of the aPAD for females 13-49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ipconazole from food and water will utilize <1% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. There are no residential uses for ipconazole.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, ipconazole is not registered for any use patterns that would result in short-term residential exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is

necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for ipconazole.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, ipconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for ipconazole.

5. *Aggregate cancer risk for U.S. population.* Ipconazole has been classified as not likely to be carcinogenic, and is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to ipconazole residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) (AC/3020)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry



Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for ipconazole on vegetable, legume, group 6.

#### *C. Revisions to Petitioned-For Tolerances*

The petitioner requested a tolerance for residues of ipconazole in or on “legume vegetables succulent or dried, crop group 6”. EPA is correcting the commodity term and establishing a tolerance for “vegetable, legume, group 6”.

### **V. Conclusion**

Therefore, tolerances are established for residues of ipconazole (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) in or on vegetable, legume, group 6 at 0.01 ppm. EPA is revising the tolerance

expression for ipconazole to clarify that metabolites and degradates are covered by the tolerances and to specify how compliance with the tolerances is to be measured. The existing tolerances for pea and bean, dried shelled, except soybean, subgroup 6C at 0.01 ppm and soybean, seed at 0.01 ppm will be removed from paragraph (a) of §180.646 as these tolerances are encompassed within vegetable, legume, group 6.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 12, 2014

Lois Rossi,  
*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.646:

- a. Revise the introductory text in paragraph (a).

- b. Remove “Pea and bean, dried shelled, except soybean, subgroup 6C”, and “Soybean, seed” from the table in paragraph (a).

- c. Add alphabetically “Vegetable, legume, group 6” to the table in paragraph (a).

The amendments read as follows:

**§180.646 Ipconazole; tolerances for residues.**

(a) *General.* Tolerances are established for residues of ipconazole, including its metabolites and degradates, in or on the commodities listed in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring only ipconazole (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol) in or on the commodity.

Commodity	Parts per million
* * *	* * *
Vegetable, legume, group 6	0.01

\* \* \* \* \*